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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/225,080	01/04/1999	JANICE AU-YOUNG	PF-0066-2-DI	2905

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1642	22

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
09/225,080	Au-Young
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Mar 25, 2003* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see NOTE below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s):
see attached

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attached

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *none*

Claim(s) objected to: *40 and 42*

Claim(s) rejected: *39 and 41*

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ .

10. ☐ Other:

Response to Amendment

1. The rejection of claims 39-42 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicants amendment.

2. The rejection of claims 39 and 41 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for reasons of record of parts (a)of the rejection of section 6 of the previous Office action. Applicant has pointed out that only claims 39 and 41 were drawn to the variants. It is noted that this is a typographical error on the examiners part.

Claims 39 and 41 are drawn in part to polypeptides comprising an amino acid sequence having at least 90% sequence identity to SEQ ID NO:2 wherein the amino acid sequence is expressed on the surface of stem cells. The specification discusses the full length SCAH-2 (SEQ ID NO:2) as being a stem cell antigen or as functioning to inhibit the activation of natural killer cells. However, the specification does not identify variants of SEQ ID NO:2 that would be expressed on the surface of stem cells, or the organs or tissues which would have said stem cells, such as prostate tissue or bone marrow. As the specification does not provide a written description of the amino acid sequences of the claimed variants to SEQ ID NO:2 that are exposed on the cell surface, one of skill in the art could not use the invention as one of skill in the art would need to where to look for said stem cells, and the specification provides no teachings as to know the organ or tissues harboring said stem cells in order to isolate said cells and determine the sequence of the variant polypeptide. Due to these reasons, one of skill in the art would be forced into undue experimentation without reasonable expectation of success in order to practice the invention as claimed. Applicant argues that the specification is enabling for where to isolate

variants because the specification teaches libraries derived from cancerous tissues where SCAH-2 is found. This has been considered but not found persuasive. Given that the specification does not provide any objective evidence that said variants exist in the tissues from which the disclosed cDNA libraries were derived, one of skill in the art would be subject to undue experimentation without reasonable expectation of success in order to make and use the broadly claimed SCAH-2 variant polypeptides. These presence of the SCAH-2 as SEQ ID NO:2 or the cDNA encoding it, does not guarantee that the same tissues would harbor the claimed variants.

Applicant argues against both a rejection under 112, first for lacking adequate written description and a rejection for lacking enablement for the variants claimed. The arguments for lacking adequate written description have not been considered as the rejection was for lack of enablement on how to make and use the instant variants of SEQ ID NO:2. Applicant argues that given SEQ ID NO:2, one of ordinary skill in the art would recognize variants of SEQ ID NO:2 having 90% sequence identity to SEQ ID NO:2, as those polypeptides which when assayed have the stem cell antigen activity of being expressed on the surface of stem cells. This has been considered but not found persuasive as the specification does not teach how to differentiate stem cells from non-stem cells, or cells which are committed progenitor cells. Without an independent determination if a cell is a stem cell or a non-stem cell, one of skill in the art could not determine if a polypeptide sequence having 90% sequence identity to SEQ ID NO:2 is indicative of a stem cell as it is required by the claim that said variant be expressed on the surface of a stem cell.

Applicant further argues that the specification has taught residues which are conserved across a number of stem cell antigens and would be likely to be important for function. However, the limitations are not part of the claim.. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, with regard to the presence of C-terminal hydrophobic sequences for GPI attachment, it is noted that many proteins anchored to the cell membrane would have said hydrophobic sequence for attachment. Applicant argues

that assays to determine functional activity are considered routine experimentation when identifying functional sequence variants. This has been considered but not found persuasive. SEQ ID NO:2 has no disclosed functional activity that could be measured in an assay. The utility associated with SEQ ID NO:2 is passive with regard to indicating a cell as a stem cell. One of skill in the art would use an antibody which specifically binds to said protein to positively characterize a cell as a stem cell. There is no objective evidence in the specification or any art of record to indicate that the protein has receptor binding, signaling or other enzymatic activity which could be assayed.

3. Claims 40 and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

July 2, 2003